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**Tissue Engineered Devices for Periodontal Indications  
DR. Michael McGuire  
Presentation to FDA  
June 24, 2002**

**Good morning, my name is Michael McGuire. I am a periodontist in full time private practice in Houston Texas. I am also a clinical assistant professor at the University of Texas Health Science Center in Houston and San Antonio and currently the immediate past president of the American Academy of Periodontology. I am a consultant on evidence-based dentistry to the ADA Council on Scientific Affairs, and I serve on the editorial board of several journals on periodontics and dental implants. I have been the principal investigator in numerous practice based clinical trials on new dental technologies and have published broadly in peer reviewed Journals in this field and have received the Clinical Research Award from the AAP.**

**I am also a physician sponsor of a device investigation to evaluate the safety and efficacy of Dermagraft, a commercially approved product of Advanced Tissue Science as a substitute for autologous palatal grafts. As a result of all of this, I feel I am qualified to speak to you about the issues before this hearing today.**

**I requested the opportunity to speak at this hearing so that I might share with you my experience with tissue-engineered devices in the periodontal arena, and my views on the need for this important technology to reach the market in as expeditious and least burdensome means as possible.**

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Assuring that there is adequate hard and soft tissue around teeth is critical to periodontal health. Periodontal disease is a widespread problem in the U.S. The Surgeon General has reported that the percentage of adults with severe periodontal disease is significant, and increases with age, so we therefore can expect it to be an increasing public health problem as the baby boomers age.<sup>1/</sup> According to the American Dental Association, approximately 400,000 people undergo periodontal surgery involving soft tissue grafts annually in the U.S. These statistics highlight the importance of ensuring that there are adequate treatments in place to address this significant health problem.

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In order to cover exposed roots and repair damaged gums, we usually harvest donor tissue from the roof of the patient's mouth and graft it onto the deficient area. Autogenous grafts require a second surgical site to harvest donor tissue, which causes increased discomfort and risks for the patient. To compound the problem, because of anatomic and structural limitations, patients often do not have adequate supplies of autogenous tissue to cover multiple teeth with extensive soft tissue loss. As a result, grafting procedures often require multiple surgeries. Because of the limitations associated with this technique, we are looking for a viable alternative that will provide unlimited supplies of "off the shelf" tissue

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<sup>1/</sup> Oral Health in America: Report of the Surgeon General. Office of the Surgeon General, U.S. Public Health Service, May 25, 2000.

for periodontal soft tissue repair, thus reducing pain and discomfort to the patient, and limiting the number of surgeries that the patient has to undergo.<sup>2/</sup> (Slide)

Tissue-engineered products containing live human cells that are seeded onto a synthetic matrix show great promise for fulfilling this need. Most importantly, because they provide unlimited supplies of viable tissue, they reduce the need for additional surgeries, or multiple surgical sites. Larger areas can be treated in a single surgery without requiring any donor tissue, thus reducing the additional discomfort and risk to patients.<sup>3/</sup>

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I recently conducted a pilot study in 20 periodontal patients to assess the safety and efficacy of Dermagraft in establishing a functional zone of attached gingiva. The preliminary results of this study, demonstrated that Dermagraft did generate new attached gingiva.

Because of the promise of this technology and the fact that it reduces risk for my patients while offering all of the benefits associated with autogenous grafts, there should be no regulatory burdens that unduly impede its availability.

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<sup>2/</sup> See, e.g., Reiser, G.M., et al. 1996. The subepithelial connective tissue graft palatal donor site: anatomic considerations for surgeons. *Int. J. Periodontics Restorative Dent.* 16(2):130-7; Fowler, E.B. and Breault, L.G. 2000. Root coverage with an acellular dermal allograft: A three-month case report. *J. Contemporary Dental Practice:* 1(3):1-8; Kaigler, D. and Mooney, D. 2001. Tissue engineering's impact on dentistry. *J. Dental Education* 65(5):456-62.

<sup>3/</sup> See, e.g., Baum, B.J. and Mooney, D.J. 2000. The impact of tissue engineering on dentistry. *J. Amer. Dental Assoc.* 131:309-18; Fowler, E.B. and Breault, L.G. 2000. Root coverage with an acellular dermal allograft: A three-month case report. *J. Contemporary Dental Practice:* 1(3):1-8;  
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**Tissue engineered products in the periodontal area, including those with cellular components, serve the function of providing a matrix for regeneration and repair. Dermagraft performed effectively in my study as a substitute for autologous palatal connective tissue. We biopsied some of the sites we treated, and the histology revealed normal looking connective tissue covered by keratinized epithelium on both test and control teeth. A blinded examiner was not able to distinguish which biopsy was generated using Dermagraft vs. the palatal donor tissue.**

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**I understand that structural tissue-derived periodontal products and other products that make biological claims about regeneration and repair historically have been regulated by the Center for Devices. I further understand that a vast array of dental products – including products for periodontal grafting, augmentation, and reconstruction; membranes for guided tissue regeneration; and aids to wound healing – have resulted from these review processes.**

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**It is my understanding that the necessary periodontal and dental expertise resides in this Center, and that the periodontists and dentists in the Dental Review Branch have evaluated tissue regeneration and other products for many years, and are familiar with the product design and performance characteristics most important to periodontal products. In my**

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**Henderson, R.D. 1999. Root coverage using Alloderm<sup>®</sup> acellular dermal graft material. J. Contemporary Dental Practice: 1(1):1-10.**

dealings, as an investigator, with this branch of the FDA, I have personally always found them to be very knowledgeable about the nuances of periodontal clinical trial design.

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In addition to that, as an officer of AAP, I also have been involved in initiatives that spanned over a 10 year period, aimed at sharing knowledge and educating the Dental Device Branch about clinical trial design and what constitutes a clinically significant outcome. As a result, I consider the Dental Device Branch to be the center of expertise in the FDA in this area.

I believe that the dental experience and background found in the Dental Device Group is optimal for the review of structural products for periodontal grafting, like ATS' product Dermagraft. The mouth is a unique environment, with special concerns due to its high bacterial load, and mechanical challenges that need to be addressed by a group that has experience with clinical trial design and outcome assessment in this area.

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In conclusion, there is a great need for viable alternatives to autogenous donor tissue for periodontal grafting. As our population continues to age, and periodontal disease becomes more widespread, there will be an increased need for alternatives to the autogenous graft. As a periodontist, I am very excited about the prospect of having tissue-engineered periodontal devices available to treat my patients and see them as offering immediate benefits while reducing the risk to my patients. It is my hope that the jurisdictional

**discussions today will not result in additional regulatory obstacles that could slow or impede the continued development, and patient access to, these important products.**

**Thank you for the opportunity to speak before you today.**